CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

201-16300

August 1, 2006

Mr. Jeffrey Taylor
U.S. Environmental Protection Agency
EPA East Building
Room 4410H (MC7405)
1200 Pennsylvania Ave, NW
Washington, DC 20004
202.564.8828

Dear Mr. Taylor:

On June 9, 2006 CPMA submitted to you six test plans prepared by committees of the Color Pigments Manufacturers Association, Inc. (CPMA) under EPA's High Production Volume Chemical Testing Program:

- Test Plan for 6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid) and 2-Amino-5-chloro-ptoluenesulfonic acid (C Amine),
- Test Plan 3,3' Dichlorobenzidine Dihydrochloride,
- Test Plan for C. I. Pigments Violet 19, Red 122, and Dihydro Quinacridone,
- Test Plan for C. I. Pigment Red 48 (Barium), C.I. Pigment Red 48 (Calcium) and C.I. Pigment Red 52 (Calcium),
- Test Plan for C.I. Pigment Yellow 14, and
- Test Plan for C. I. Pigment Red 49 (Barium)

The test plans were formatted incorrectly and were actually earlier drafts. As a result, we are submitting the revised test plans.

Two test plans have already been posted on the EPA web site: Test Plan for C. I. Pigment Red 49 (Barium) and Test Plan for C6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid) and 2-Amino-5-chloro-ptoluenesulfonic acid (C Amine). Your removal of these two tests plans from the site and replacing them with the enclosed revised test plans is appreciated.

The remaining test plans that were previously sent and have not yet been posted should be disregarded, and replaced with the corrected versions.

Thank you for your attention to this.

Sincerely,

J. Lawrence Robinson
President

300 North Washington Street, Suite 102 • Alexandria, Virginia 22314 • (703) 684-4044 • FAX: (703) 684-1795
Mailing Address: P.O. Box 20839 • Alexandria, Virginia 22320-1839 • e-mail: cpma@cpma.com

August 8, 2006

Dear NCIC,

Please replace the previous 6 CPMA test plan and robust summary submissions (AR201-16298 through AR201-16303) from June 2006 with these newly corrected 6 CPMA test plan and robust summary submissions. CPMA phoned me to say that no substantial information was changed; only the formatting was corrected. Please give these new submissions the same AR numbers that you had previously used for them, and also process this cover page of mine along with CPMA's new cover page that they have attached to the new materials.

Thank you,
Jeffrey Taylor

Jeffrey A. Taylor
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division
EPA East -- Room 4410-H, Mail Code 7405M
1200 Penn Ave NW, Washington, DC 20004
Tel (202) 564-8828, Fax (202) 564-4775

201-16300

HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM

TEST PLAN
FOR
C.I. Pigment Yellow 14
(CAS NO.: 5468-75-7)

PREPARED BY:
COLOR PIGMENT MANUFACTURERS ASSOCIATION, INC.
DIARYLIDE PIGMENTS COMMITTEE

June, 2006

TABLE OF CONTENTS

OVERVIEW

The Diarylide Pigments Committee ("DPC") of the Color Pigment Manufacturers Association, Inc. (CPMA) and its member companies hereby submits for review and public comment this test plan for C.I. Pigment Yellow 14 CAS NO.: 5468757) under the Environmental Protection Agency's (EPA) High Production Volume (HPV) Challenge Program. It is the intent of the DPC and its member companies to use existing data and predictive computer models to adequately fulfill the Screening Information Data Set (SIDS) for the various physicochemical, environmental fate, ecotoxicity , and human health effects endpoints.

C.I. Pigment Yellow 14 (CAS NO.: 5468757) is a stable solid. This chemical is used to provide color for many products in the printing ink, paint and plastic industries. This chemical is stable in neutral solutions, and is considered as "not readily biodegradable".

TEST PLAN SUMMARY

CAS No.5468757	Information	OECD Study	Other	Estimation	GLP	Acceptable	New Testing Req.
STUDY	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYSICAL-CHEMICAL DATA							
Melting Point	Y	-	Y		N	Y	N
Boiling Point	N/A	-	-		N	Y	N
Vapor Pressure	Y	-	Y		N	Y	N
Partition Coefficient	Y	-	Y		N	Y	N
Water Solubility	Y	-	Y		Y	Y	N
ENVIRONMENTAL FATE ENDPOINTS							
Photodegradation	Y	N	-	Y	N	Y	N
Stability in Water	N\A	Y			N	Y	N
Biodegradation	Y	Y	Y	-	N	Y	N
Transport between Environmental Compartments	Y	Y	-	Y	N	Y	N
(Fugacity)	Y			Y		Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y	Y	-	-	Y	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	Y		-	Y	Y	N
Toxicity to Aquatic Plants	Y	Y		-	Y	Y	N
TOXICOLOGICAL DATA							
Acute Toxicity	Y	Y	Y	-	Y	Y	N
Repeated Dose Toxicity	Y	Y		-	Y	Y	N
Genetic Toxicity – Mutation	Y	Y	Y	-	N	Y	N
Genetic Toxicity – Chromosomal Aberrations	Y	Y	Y	-	N	Y	N
Developmental Toxicity	Y	Y		-	Y	Y	N
Toxicity to Reproduction	Y	Y		-	Y	Y	N

TEST PLAN DESCRIPTION FOR EACH SIDS ENDPOINT

A. Physicochemical

Melting point - A value for this endpoint was obtained from a reputable journal and through surrogate data.

Boiling Point - A value for this endpoint was obtained using a computer estimation-modeling program within EPIWIN.

Vapor Pressure - A value for this endpoint was obtained using surrogate data .

Partition Coefficient - Due to insolubility in both water and octanol experimental values cannot be reliably obtained and estimations are not accurate or reliable. A measured solubility value in octanol for is provided.

Water Solubility - A calculated value based on the experimental melting point was obtained for this endpoint using a computer estimation-modeling program within EPIWIN. Surrogate data is also cited.

Conclusion: All end points have been satisfied by utilizing data obtained from the various physical chemical data modeling programs within EPIWIN or using measured values. The results of the various computer estimation models within EPIWIN have been noted by the Agency as acceptable in lieu of actual data or values identified from textbooks. No new testing is required.

B. Environmental Fate

Photodegradation - A value for this endpoint was obtained using AOPWIN, a computer estimation-modeling program within EPIWIN (1) and through the use of surrogate data.

Stability in Water - A value for this endpoint was obtained from analysis of a surrogate substances

Biodegradation - This endpoint was satisfied through the use of an OECD-301C test. The study was

Fugacity - A value for this endpoint was obtained using the EQC Level III partitioning computer estimation model within EPIWIN.

Conclusion: All endpoints have been filled with data utilizing acceptable methodologies and of sufficient quality to fulfill these endpoints. No new studies are being proposed.

C. Ecotoxicity Data

Acute Toxicity to Fish - This endpoint is filled by data from a study that followed OECD TG-203 and was conducted under GLP assurances for surrogate substances.

Acute Toxicity to Aquatic Invertebrates - This endpoint is filled by data from a study that followed OECD TG-202 and was conducted under GLP assurances for a surrogate substance.

Toxicity to Aquatic This endpoint is filled by data from a study that followed OECD TG-201 for plants surrogate substances.

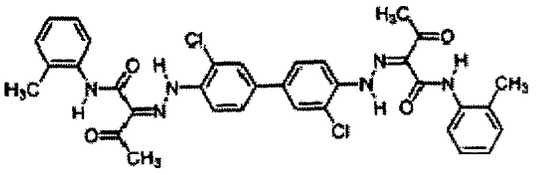
Bioaccumulation	This endpoint is filled by data from a GLP study for a surrogate substance.
Conclusion:	All endpoints have been satisfied with data from studies that were conducted using established OECD guidelines. In total, these currently available studies are of sufficient quality to conclude that no additional testing is needed.
D. Toxicological Data	
Acute Toxicity -	This endpoint is filled by oral exposure data from various published and unpublished references to studies completed in 1961, 1968, 1972, 1976, 1985 and 1992 precise information on protocols followed is not available. Nevertheless, given the number of studies and the consistent results this data is considered "reliable with restrictions". Data for Skin sensitization, skin irritation and eye irritation are also available.
Repeat Dose Toxicity -	This endpoint is filled by data from a study that followed OECD TG-422 for a surrogate substance.
Genetic Toxicity	
Mutation -	This endpoint is filled by published values supplied by manufacturers and data from a study that followed OECD TG-471 and 472 for a surrogate substance.
Aberration -	This end point is filled by published values supplied by manufacturers and data from a study that followed OECD TG-473 for a surrogate substance.
Developmental Toxicity -	This endpoint is filled by data from a study that followed OECD TG-422 for the a surrogate substance.
Reproductive Toxicity -	This endpoint is filled by data from a study that followed OECD TG-422 for the a surrogate substance.
Conclusion:	All endpoints have been satisfied with data on C. I. Pigment Yellow 14 or through the use of structural surrogates, which are of sufficient quality to conclude that no additional testing is needed.

Rationalization for Use of Surrogate Data

As a means of reducing the number of tests that may be conducted, the EPA allows for the use of data from structurally similar compounds to characterize specific SIDS endpoints (US EPA 1999a). Accordingly, the DPC believes that data from the available studies for C.I. Pigment Yellow 13 (CAS No. 5102830) C.I. Pigment Yellow 12 (CAS No. 6358856) and C.I. Pigment Yellow 83 (CAS No. 5567157) meet the needed criteria for use as surrogates in the completion of some SIDS endpoints. These color pigments are derived from diarylide compounds acetoacetanilide or similar compounds and 3,3' dichlorobenzidine. As is readily seen by their structures below, C.I. Pigment Yellow 14, C.I. Pigment Yellow 12, C.I. Pigment Yellow 13 and C.I. Pigment Yellow 83 only differ by the substitution of the outer aniline rings, e.g. methyl, chloro and methoxy. They are expected to display essentially the same trend in environmental, ecotoxicological and toxicological behavior based on the available data. This modification does not significantly alter the basic physicochemical properties or the basic biological effects. All three compounds have a similar acute toxicity value. Accordingly, the extensive data developed for the international HPX program for C.I. Pigment Yellow 13, C.I. Pigment Yellow 12 and C.I. Pigment Yellow 83 have been used to fulfill a number of the SIDS endpoints for C.I. Pigment Yellow 14. We note that these three compounds (without C.I. Pigment Yellow 14) have been accepted as a test grouping in the OECD SIDS program. It is our understanding that all testing for the basic SIDS endpoints for the three diarylide pigments (other than C.I. Pigment Yellow 14) is complete.

Common Name: C.I. Pigment Yellow 14,

Structure:

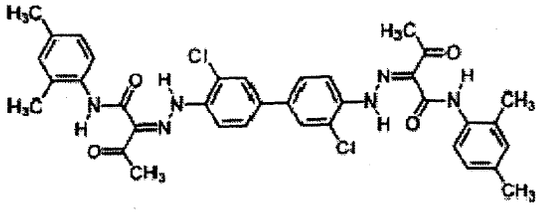


Chemical Name: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Melting Point: 360
Boiling Point: Solid
Density 1.45 kg/m ^{3} at 20 °C
Acute Toxicity: LD50>5000 mg/kg,

Common Name C.I. Pigment Yellow 13

Structure:

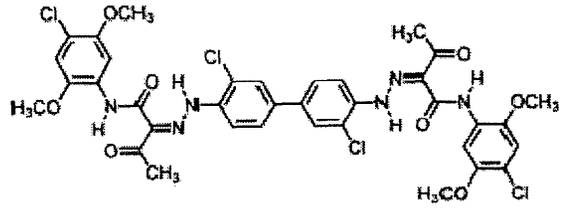


Chemical Name Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Melting Point 350
Boiling Point: Solid
Density 1.45 kg/m ^{3} at 20 °C
Acute Toxicity: LD50> 3,000 mg/kg,

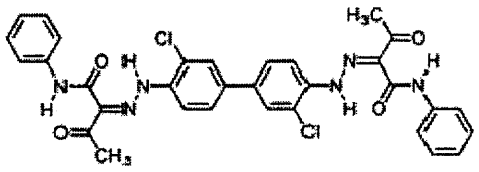
Common Name C.I. Pigment Yellow 83

Structure:



Chemical Name	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Melting Point	400 °C
Boiling Point:	Solid
Density	1.37g/cm ^{3} at 20 °C
Acute Toxicity:	LD50>1,750 mg/kg,
Water Solubility :	OECD TG 105 8.9 mg/l at 25 °C
Common Name	C.I. Pigment Yellow 12

Structure:



Chemical Name	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-
Melting Point	320 °C
Boiling Point:	Solid
Density	1.37g/cm ^{3} at 20 °C
Acute Toxicity:	LD50>1,750 mg/kg,
Water Solubility :	N/A

SIDS DATA SUMMARY

Physical Chemical Endpoints

Data assessing the various physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility) for C.I. Pigment Yellow 14 were also obtained from experimental calculations estimations using the models within EPIWIN and surrogate substances. These data indicate that C.I. Pigment Yellow 14 is a stable solid at room temperature, is largely insoluble in octanol and is also insoluble in water .

Environment

The pigments are a solid with a very low vapor pressure, a water solubility of <20 □g/L and a calculated Log Kow of 6.8-8.1. They have a calculated half-life for photo-oxidation of 1.7 – 4.5 hours (indirect reaction with OH-radical) and are expected to be hydrolytically stable. Fugacity modeling (Mackay Level III) predicts that the pigments will partition primarily to sediment (98%) if released to the aquatic compartment. Based on the log Kow the pigments have high potential for adsorption to soil (predicted Log Koc 4.0 – 5.3). The experimental data indicate that the pigments are not biodegradable.

The acute LC50/EC50 of the pigments to fish and daphnia are above the water solubility limit. In 72h algal tests with Pigment Yellow 12 and 83, the ErC50s were also above the water solubility limit. Although some effects on biomass were reported in one algal study for Pigment Yellow 12 (below 50%), significant fluctuations were observed in the algal results. Further algal testing on Pigment Yellow 12 indicated no effects at solubility and these are considered key studies

based on a weight of evidence approach. The NOEC in a daphnia chronic reproduction study was set at the water solubility limit as no effects were reported at the nominal concentration of 1 mg/L. No toxicity towards micro-organisms was observed at the solubility limit. Based on the very low water and n-octanol solubility exposure of aquatic organisms to the pigments is expected to be low. There are no sediment or terrestrial effect data. Partitioning to sediment may be possible based on the high sorptive potential (Koc=4.0-5.3).

Acute Toxicity

The acute oral LD50 values for rats are >3000 mg/kg bw for Pigment Yellow 13 and >1,750 mg/kg bw for Pigment Yellow 83. The acute oral LD50 values derived from studies in experimental animals are >1,750 mg/kg bw for the three Diarylide Yellow Pigments. For acute dermal toxicity a single LD50 of >3,000 mg/kg bw is available for Pigment Yellow 13. No deaths or clinical signs of toxicity were observed following oral or dermal exposure. The inhalation LC50 available is >1,384 mg/m3 for Pigment Yellow 13. Tachypnoea was observed, although all animals recovered and no gross abnormalities were observed at necropsy.

Human Health

Standard single exposure toxicokinetics studies indicate essentially no potential for uptake via the oral and dermal routes. However, following repeated oral exposure at high dose levels, there is some evidence that a very limited uptake of the compound (or its impurities) could occur, based on observations of staining of the mucosa surfaces of internal organs (although the possibility of contamination during necropsy cannot be excluded). In an oral reproductive developmental screening study, staining of the pups could indicate a potential for limited placental transfer, again at a high dose level. Given that the pigment yellows are essentially not absorbed into the body, metabolism is not relevant. However, the presence of very low levels of 3,3'-dichlorobenzidine has been demonstrated in two studies using very sensitive techniques following oral administration of some yellow pigment compounds. It seems likely that this is due to the presence of a mono-azo impurity in some of the yellow pigment parent compounds, which is absorbed and subsequently metabolized. No 3,3'-dichlorobenzidine was found in the urine of experimental animals after exposure orally or via the lungs in long term studies. Following ingestion, the vast majority of the pigments are excreted unchanged in the feces.

All three pigments may be minimally irritating when in contact with the skin. Based on the available data the pigments have a minimal to slight potential for eye irritation. There is no indication that the three pigments are sensitizers.
No adverse effects were seen after 4-7 weeks oral administration of Pigment Yellow 12 at 1000 mg/kg/day (NOAEL), the highest dose tested in a well conducted and reported test of repeated dose toxicity (OECD TG422) study. Furthermore, in the cases of Pigment Yellow 12 and 83, no toxicologically significant effects were observed in a range of chronic toxicity studies of lesser quality (in terms of reporting) in rats and mice at doses up to 6500 mg/kg/day. Based on the kinetics of the three pigments and the chemical similarities, it can be concluded that these findings can be extrapolated to all four pigments.

For the inhalation route the effects seen are related to the deposition of dust particles in the lungs, leading to Pigment Yellow 13 related effects even at the lowest exposure concentration of 54 mg/m3 (local LOAEL). Systemically no effects were observed at the highest concentration tested, 410 mg/m3 (systemic NOAEL).

All three pigments are not genotoxic in bacterial tests. Pigment Yellow 12 did not induce clastogenic effects in mammalian cells. Based on the chemical similarities between the three pigments, it is predicted that all three Yellow Pigments will not induce chromosomal changes in mammalian cells. There are no *in vitro* data to suggest that the pigments are genotoxic *in vivo*.

No increased tumor incidence after treatment with Pigment Yellow 12 and 83 were observed in several long-term studies in rats and mice (NOAEL (rat) > 630 mg/kg; NOAEL (mouse) > 1,960 mg/kg). Based on chemical similarity it can be concluded that the three pigments are not carcinogenic.
It can be concluded that Pigment Yellow 12 does not have any adverse effects on reproductive parameters. There was no evidence of teratogenicity. The NOAEL for maternal and reproductive toxicity is >1,000 mg/kg bw. Supporting evidence is also available from the fact that no changes on the reproductive organs were observed in the studies of repeat dose

toxicity and carcinogenicity study with Pigment Yellow 83. In view of the structural similarities and similar kinetics no further testing is planned for C.I. Pigment Yellow 14

Conclusion

All endpoints have been satisfied with data, on C. I. Pigment Yellow 14 or through the use of structural surrogates, which are of sufficient quality to conclude that no additional testing is needed. Since these substances are extremely stable and insoluble in water, ink formulations or other uses such as paints and plastic formulations, and since these substances are encapsulated in these applications, exposure to these products in use is limited.

EVALUATION OF DATA FOR QUALITY AND ACCEPTABILITY

The collected data were reviewed for quality and acceptability following the general US EPA guidance (3) and the systematic approach described by Klimisch *et al.* (4). These methods include consideration of the reliability, relevance and adequacy of the data in evaluating their usefulness for hazard assessment purposes. This scoring system was only applied to ecotoxicology and human health endpoint studies per EPA recommendation (5). The codification described by Klimisch specifies four categories of reliability for describing data adequacy. These are:

1. Reliable without Restriction: Includes studies or data complying with Good Laboratory Practice (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.

2. Reliable with Restrictions: Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.

3. Not Reliable: Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.

4. Not Assignable: Includes studies or data in which insufficient detail is reported to assign a rating, e.g., listed in abstracts or secondary literature.

REFERENCES

1. EPIWIN, Version 3.10, Syracuse Research Corporation, Syracuse, New York.

2. US EPA. (1999). The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. OPPT, EPA.

3. USEPA (1998). 3.4 Guidance for Meeting the SIDS Requirements (The SIDS Guide). Guidance for the HPV Challenge Program. Dated 11/2/98.

4. Klimisch, H.-J., Andreae, M., and Tillmann, U. (1997). A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. *Regul. Toxicol. Pharmacol.* 25:1-5.

5. USEPA. 1999. Determining the Adequacy of Existing Data. Guidance for the HPV Challenge Program. Draft dated 2/10/99.

I. General Information

CAS Number: C.I. Pigment Yellow 14 (CAS NO.: 5468757)

Name: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

II. Physical-Chemical Data

A1. Melting Point

Test Substance

Test substance: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Remarks:

Method

Method: Measured

Remarks:

Results

Melting point value: 360 °C

Remarks:

References NPIRI, 2000

Other

Data is consistent with melting points for the class of pigments and other available measurements

A2. Melting Point

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Method:	Measured
Remarks:	2002

Results

Melting point value:	350 °C
Remarks:	Decomposition is reported at 200 °C

References

IUCLID Database
reliable with restrictions

Other

Data is consistent with melting points for the class of pigments and other available measurements.

B. Boiling Point

Test Substance

Test substance:	SOLID
Remarks:	

Method

Method:	
Remarks:	

Results

Boiling point value:	
Remarks:	

References

Other

C1. Vapor Pressure

Test Substance

Test substance:	C.I. Pigment Yellow 14 (CAS NO.: 5468757)
Remarks:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Method

Method:	Estimation
Remarks:	

Results

Vapor pressure value:	2.4E-23 Pa
Temperature:	
Remarks:	

References

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

C2. Vapor Pressure

Test Substance

Test substance: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Remarks:

Method

Method: Estimation Modified Grain Method

Remarks:

Results

Vapor pressure value: 2.05 E-022 mm Hg

Temperature: 25 °C

Remarks:

References MPBPWIN v. 1.41, Syracuse Research Corporation, Syracuse, New York

Other

D. Partition Coefficient

Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Remarks:

Method

Method: Octanol-water

Remarks:

Results

Value: 8.1.mg/l

Remarks: Calculated 2002 (EPI WIN 3.1)

References

Log Kow partition coefficient cannot be meaningfully determined for this compound and its structural surrogates, solubility in water and octanol are too low to produce a meaningful value.

Other

E. Water Solubility

Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Remarks:

Method

Method: About 5 mg of the pigment is dispersed in 30 ml of water and shaken for a period of seven hours at a controlled temperature of 80 °C, followed by a second, third and fourth period at 25 °C (16,40 and 64 hours) to approach the equilibrium between the pigment in solution and the solid. The clear solution is measured spectrophotometrically.

Remarks: Measured Value

Results

Value: <.02 mg/L

Temperature: 25 °C

Description: Very Low Solubility

Remarks:

References

Az, R., Investigations into the solubility of selected generic organic pigments in water and n-octanol, Clariant, unpublished results, July 5, 2001.

Other

The author stated that the very low solubility of pigment in water or octanol did not allow for any absorbance measurement.

Environmental Fate Endpoints

A. Photodegradation

Test Substance

Test substance: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Remarks:

Method

Method: Estimate

Test type: Water\sunlight

Remarks:

Results

Temperature:

Degradation Rate

: Half-life

Ozone reaction: 3.7 Hours, No ozone reaction estimation

Remarks:

Conclusions

References

AOPWIN v. 1.91, Syracuse Research Corporation, Syracuse, New York

Other

B. Stability in Water

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	estimate
Test type:	
GLP:	
Remarks:	

Results

Half-life:	
Percent hydrolyzed in 5 days (120 hs) at 50 °C :	
Remarks:	Hydrolysis rate is extremely slow. Under the conditions of an anaerobic biodegradation test with a similar compound (biazoaryl pigment), no hydrolysis within 56 days.

Conclusions

Data Quality

Remarks:

References HYDROWIN v. 1.67, Syracuse Research Corporation, Syracuse, New York

Other

C. Biodegradation

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	OECD 301C
Test type:	Biological Oxygen Demand (BOD)
GLP:	Yes
Year:	1992
Remarks:	Degree of degradation after 28 days (Japanese standard activated sludge)

Results

Results:	C.I. Pigment Yellown13 is not readily biodegradable
Remarks:	

Conclusions

Data Quality

Remarks:

References

Madsen, T., Aerobic biodegradability of Pimatex Yellow 2GL- modified MITI test (I), VkI Water Quality Institute, 1995 (41). See also IUCLID DATASET C.I. Pigment Yellow 13.

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks: 4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Test type: Estimation
Model used: Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
Remarks:

Results

Model data and results:

Distribution (%)	
Air	.000162
Water	.656
Soil	53.4
Sediment	45.9

Remarks:

Conclusions

Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

References

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210.

Other

The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15(9)**, 1618-1626 and 1627-1637.

IV. Ecotoxicity

A. Acute Toxicity to Fish

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was 94.5%

Method

Method:	
Test type:	OECD 203
GLP:	Flow through
Year:	yes
Species/strain:	2002
Analytical monitoring:	Bracgydanio rerio (zebrafish)
Exposure period:	Exposure solutions, temperature, pH, dissolved oxygen
Remarks:	96-Hour A group of 7 fishes were exposed to 2 nominal concentrations(0 and 100 mg/L),

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Biological observations:	
Statistical methods:	No effect, 96 hour EC-50 exceeds the maximum solubility of the test substance
Remarks:	

Conclusions Test substance is not toxic to fish

Data Quality

Reliability:	Reliable without restrictions
Remarks:	

References A. Schnurstein, Pigment Yellow 83, standard technical grade; 96 hour acute toxicity study in zebrafish (Danio rerio)/PT02-0300, Aventis Pharma Deutschland GmbH, 2002. See also IUCLID Dataset C.I. Pigment Yellow 83, p.21/54

Other

B. Acute Toxicity to Aquatic InvertebratesTest Substance

Test substance:

Remarks:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	Purity was 98.%
Test type:	
GLP:	
Year:	Directive 92/69/EC.2
Species/strain:	Static
Analytical monitoring:	Yes
Exposure period:	2002
Remarks:	Daphnia (*Daphnia magna*) Temperature, pH and dissolved oxygen 72 Hours

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Reproduction	100 mg/L
Biological observations:	
Statistical methods:	immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
Remarks:	

20 daphnids were exposed to2 nominal concentrations (0 and 100 mg/L)

Conclusions

Data Quality

Reliability:

Remarks:

Reliable without restrictions

References

This was a well-documented OECD guideline study conducted under GLP assurances.

Other

Migchielsen, M.H.J., Acute Toxicity Study in Daphnia Magna With C.I. Pigment Yellow 12, Project No. 341303, Notox BV, 2002

B2. Chronic Toxicity to Aquatic InvertebratesTest

Substance

Test substance:

Remarks: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo

Purity was 99.7.%

Method

Method: OECD 211
Test type: Semi -Static
GLP: Yes
Year: 1999
Species/strain: Daphnia (*Daphnia magna*)
Analytical monitoring: no
Exposure period: 21 Days
Remarks:

Results

Nominal concentration:
Measured concentration:
Endpoint value:
Reproduction
Biological observations: 0 and 1 mg/L
Statistical methods: Wilcoxon Test
Remarks: immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
No. of Living offspring 126, 115 No. of Dead offspring 32, 30

Conclusions

The test was performed at concentration far above water solubility. The particulate matter may cause physical interference with the daphnids, which may influence the results of the test. This renders the results from this test less suitable for risk assessment, but it is not expected that at maximum water solubility the substance will cause any effects.

Data Quality

Reliability: Reliable without restrictions
Remarks: This was a well-documented OECD guideline study conducted under GLP assurances.

References

No treatment related effects were seen.

Other

Hoechst Marion Roussel, C.I. pigment Yellow 13 Daphnia Magna reproduction test, report No. 99.0405, September 1999

C. Toxicity to Aquatic Plants

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity 94.5%

Method

Method:	Directive 92/69/EEC
Test type:	static
GLP:	Yes
Year:	2002
Species/strain:	Selenastrum capricornutum
Endpoint basis:	
Exposure period:	72 hours
Analytical procedures:	
Remarks:	

Results

Nominal concentration:	100 mg /L
Measured concentration:	
Endpoint value:	EC_{50} (72 hour) 190mg/L
NOEC:	equal to maximum solubility
Biological observations:	
Was control response :satisfactory	Yes
Statistical Methods:	ANOVA
Remarks:	

Conclusions No statistically significant inhibition of biomass and growth rate.

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Migchielsen, M.H.J. Fresh Water Algal Growth Inhibition Test With C.I. Pigment Yellow 83, Project No. 341292, Notox BV, 2002

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5dimethoxylphenyl)-3-oxobutyramide Purity was unknown
Remarks:	

Method

	Acute lethality; Other
Method:	LD_{50} estimate
Test type:	No (Pre-GLP)
GLP:	1972
Year:	unknown
Species/strain:	Oral gavage
Route of exposure:	5,000 & 10,000 mg/kg bw
Dose levels:	
Remarks:	

Results

	LD_{50} = >10,000 mg/kg.
Value:	
Deaths at each dose:	
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

	Reliable with restrictions
Reliability:	The study was conducted quite some time ago and hence many study details
Remarks:	are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.

References

Thomann P., Acute Oral Lethal Dose in Rats, Exp. No. 367/35 Ciba Geigy Ltd. 1972

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was unknown

Method

Method:	Acute lethality; OECD 401
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1984
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	5,000 mg/kg administered to animals 5 male, 5 female only 35% of the test mixture was C.I. Pigment Yellow 83

Results

Value:	
Deaths at each dose:	LD_{50} = >1,750 mg/kg.
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability:	
Remarks:	Reliable with restrictions The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for these pigments and pigments of this class.

References

Rupprich, N. and Weigard, W. Colanyl-Geib HR30 Prufung der akuten oralen Toxizitat an der mannichen und weiblichen Wistar -Ratte/ 84.0243, Hoechst AG 1984

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	Purity was unknown

Method

Method:	Acute lethality; Other
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1968
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	

Results

Value:	LD_{50} = >5,000 mg/kg.
Deaths at each dose:	
Remarks:	

Conclusions Material would be considered as not toxic.

Data Quality

Reliability:	Reliable with restrictions
Remarks:	The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.

References

Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

Repeated Dose Toxicity Test

Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1979
Species/strain:	Rat RAI f SPF
Route of exposure:	Inhalation
Duration of test:	21 days + 21 day post exposure
Exposure levels:	54, 157, 410 mg/cubic meter air
Sex:	Male and female
Exposure period:	21 days
Post-exposure observation period:	21 days
Remarks:	

Results

NOAEL (NOEL): <54mg/m3

Mortality: none

Clinical signs: none observed

Slight decrease in body weight for males and females during exposure at 410 mg/m3.food consumption: no treatment related effects, ophthalmoscopic examination: no treatment related effects, Slight increase of ASAT in males at 410 mg/m3: Hematology: no treatment related effects, at 410 mg/m3 absolute and relative weight of lungs is increased for males and females on day 21 and increased relative lung weight after recovery period: some yellow discoloration of the lungs in all treated animals, Histopathology: in the lungs focal accumulation of small brown yellow infringement particles in the cytoplasm of the hystiocytic elements in the interstitium, in alveoli, bronchi and lymphohistiocytic infiltration in all animals at 410mg/m3, no regression of lung effects observed after recovery period.

Conclusions Test substance is not significantly toxic

Data Quality

Reliability:	Reliable without restriction, This is a very well documented study.
Remarks:	

References: Sachsse, K., 21 days aerosol inhalation toxicity study in rats, Project No. 785465, Ciba Geigy Ltd. (Switzerland), 1979. C.I. Pigment Yellow 13

Other

Repeated Dose Toxicity Test

Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	Commercial purity 98%

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1984
Species/strain:	Rat
Route of exposure:	Gavage
Duration of test:	97 days
Exposure levels:	500 mg/kg bw
Sex:	Male and female
Exposure period:	
Post-exposure observation period:	
Remarks:	

Results

NOAEL (NOEL):	no treatment related changes

Conclusions Test substance is not significantly toxic

Data Quality

Reliability:	Reliable with restriction
Remarks:	

References: Colipa (1984) cited in BIBRA report 2nd Edition 1991

Other

C. **Genetic Toxicity - Mutation**

Test Substance

Test substances:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo
Remarks:	

Method

Method:	In Vitro Mutagenicity
Test type:	Ames
GLP:	No
Year:	Unknown
Species/strain:	Salmonella typhimurium
Metabolic activation:	Rat liver S9 Mix (Aroclor 1254-induced)
Concentration tested:	
Remarks:	

Results

Result:	Negative
Cytotoxic concentration:	
Precipitation concentration:	Negative
Genotoxic effects	Negative
With activation:	
Without activation:	
Statistical methods:	
Remarks:	

Conclusions

Reliable with restrictions, This is a well documented study largely following OECD guideline 471

Data Quality

Reliability:	Hoechst AG, Study of the mutagenic potential of the compound T2015-26 with salmonella typhimurium (Ames Test) Report No. 575/81, 1981
Remarks:	

References

C. **Genetic Toxicity - Mutation**

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Remarks: 96.9% pure

Method

Method: OECD471

Test type: Ames

GLP: Yes

Year: 2002

Species/strain: Salmonella typhimurium TA98, TA100, TA100, TA102, TA1535 AND TA 1537

Metabolic activation: With and without

Concentration tested: 50, 60, 500, 1600, and 5000 ug/plate with and without activation

Remarks:

Results

Result: Negative in all bacterial strains with and without activation

Cytotoxic concentration:

Precipitation concentration:

Genotoxic effects

With activation: Negative Without activation: Negative Statistical methods:

Remarks:

Conclusions

Data Quality

Reliability: Reliable without restriction Remarks:

References Kauffmann, H.M. C.I. Pigment Yellow 83 Bacterial reverse mutation test (standard plate test) and prival modification (preincubation test) report No. PT02-0190, Aventis Pharma Deutschland GmbH, 2002, C.I. PIGMENT Yellow 83,

Other

D. **Genetic Toxicity – Chromosomal Aberrations**

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-
Remarks:	

Method

Method:	Chromosomal aberration test
Test type:	CHO cells
GLP:	no
Year:	
Species/strain:	Chinese Hamster CHL Cells
Exposure period:	
Remarks:	

Results

Result:	Negative
Genotoxic effects:	Negative
Concentration tested	Without S9 1.6, 5.0, 16, 50, and 160 ug/ml With S9 .5, 1.6,5.0,16 and 50 ug/ml
Statistical methods:	
Remarks:	

Conclusions Negative

Data Quality

Reliability:	
Remarks:	Reliable with restriction

References

Other Central Data Management NTP, NTP unpublished results, NTP/NIEHS Toxicology data on C.I. Pigment Yellow 12, , IUCLID Dataset p. 48 of 68

E. **Developmental Toxicity**

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	
GLP:	OECD 422 repeated dose developmental and reproductive
Year:	
Species/strain:	2001
Sex:	Wistar Rats
Route of exposure:	Male and Female
Exposure levels:	Gavage
Actual doses received:	0, 50, 200 and 1000 mg/kg bw
Exposure period:	
Duration of test:	Males 4 weeks, Females 6 to 7 weeks
Remarks:	

Results

Maternal toxicity

NOEL: No Mortality, body weight: no treatment related effects, food consumption: no treatment related effects, clinical signs: all females showed diarrhea including controls; feces discoloration was observed in all treated females; incidental animals of all dose groups showed lethargy, hunched posture, labored respiration, salivation, chromodacryorrhea, alopecia, scabs and piloerection, hematology RBC Hb/hematocrit increased at 50 mg/kg, clinical biochemistry: ALAT/ASAT increase at 1000 mg/kg; phosphate decreased and glucose increased at 200 mg/kg; creatinine decreased at 50 mg/kg, gross pathology incidence an severity; 1/10 greenish contents of the caecum at 1000 mg/kg , no treatment related organ weight changes no histopathologic treatment related effects, number of litters = 9 at all doses
Males, no treatment related effects body weight, food consumption and functional observations, clinical signs same as females above, hemotolgy: RBC increased at 50 mg/kg, Reproductive, successful mating ,no treatment related effects, 100% mated 9/10 pregnant per dose level, none aborting duration of gestation 21-22 days, Fetal data 9 litters at all dose levels,

Parental toxic responses:

Fetal toxic responses dose:	1000 mg/kg bw parental and reproductive
Statistical Methods:	
Remarks:	

Conclusions No treatment related reproductive effects were seen in the study. NOAEL 1000 mg/kg bw for parental and reproductive toxicity

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Combined Repeated Dose Toxiicty Study with Reproduction/ Developmental Toxicity Screening Test with C.I. Pigment Yellow 12 Administered by Oral

Other Gavage in Wistar Rats May 3, 2001, C.I. Pigment Yellow 12 p. 59 of 68

F. Toxicity to Reproduction

Test Substance See Above

Test substance:

Remarks:

Method

Method:
GLP:
Year:
Species/strain:
Sex:
Route of exposure:
Exposure levels:

Exposure period:

Duration of test:
Remarks:

Results

Maternal toxicity NOEL:
Parental toxic responses:
Fetal toxic responses dose:
Statistical Methods:
Remarks:

Conclusions

Data Quality

Reliability:
Remarks:

References

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	

Method

Method:	Irritation to the rabbit eye
Test type:	eye irritation
GLP:	yes
Year:	1996
Species/strain:	rabbit, New Zealand albino (chbb:Nzw)
Route of exposure:	
Dose levels:	
Remarks:	

Results

Value:	cornea .55, iris .33 conjunctive (redness) 2.44) (Chemosis .88)
Deaths at each dose:	
Remarks:	observation times 1,24,48,72 hours, 7 days at 24 and 72 hours and 7 days with fluorescein Reversibility within 14 days

Conclusions Slightly irritating

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Eye Irritation in the Rabbit/96.0887, Hoechst AG,1996, C.I. Pigment Yellow 83

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	purity 79.1 %

Method

Method:	Skin irritation to the rabbit
Test type:	Skin irritation SEMIOCCLUSIVE
GLP:	yes
Year:	1996
Species/strain:	rabbit New Zealand albino
Route of exposure:	
Dose levels:	500 mg Vehicle, polyethylene glycol 400
Remarks:	

Results

Value:	slightly irritating reversibility - 7 days
Deaths at each dose:	
Remarks:	

Conclusions

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Dermal Irritation in the Rabbit / 96.0853, Hoechst AG, 1996, C.I. Pigment Yellow 83

Other

Chronic Dose Toxicity Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Method

Method: Chronic Toxicity
Test type: Repeated oral dose
GLP: unknown
Year: 1978
Species/strain: Sprague-Dawley Rat
Route of exposure: Oral gavage
Duration of test: 104 Weeks
Exposure levels: 0, .1, .3 and .9 %
Sex: Male and Female
Exposure period:
Post-exposure observation period:
Remarks:

Results

NOAEL (NOEL): NOAEL for Rats 630 mg/kg bw, No treatment related effects, body weight, clinical signs, food consumption, necropsy and histopathology
urine analysis (no dichlorobenzidine in urine (<LOD .3 ug/ml)

No cancerous response. No toxicity or mortality as a result of exposure

Conclusions

Data Quality

Reliability: valid with restriction
Remarks:

References Leuschner, F., Carcinogenicity Studies of Different Diarylide Yellow Pigments in Mice and Rats, Toxocol. Lett. 2, 253-260, (1978), C.I. Pigment Yellow 83. See also, Longstaff, E., An Assessment and Categorization of the Animal Carcinogenicity Data on Selelcted Dyestuffs and an Extrapolation of Those Data to an Evaluation of the Relative Carcinogenic Risk to Man, Dyes and Pigments 4, 243-304, 1983. See also Decad, G. M. et al. Fate of Water - Insoluble and Water Soluble Dichlorobenzidine - Based Pigments in Fischer 344 Rats, Journal of Toxicology and Environmental Health, Vol. 11, pp. 455-465, 1983. (Radio labeled labeled study of C.I. Pigment Yellow 12 indicating no detectable pigment in any tissue at points up to one day.)

Other

I. General Information

CAS Number:	C.I. Pigment Yellow 14 (CAS NO.: 5468757)
Name:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

II. Physical-Chemical Data

A1. Melting Point

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Measured
Remarks:	

Results

Melting point value:	360 °C
Remarks:	

References NPIRI, 2000

Other

Data is consistent with melting points for the class of pigments and other available measurements

A2. Melting Point

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Method:	Measured
Remarks:	2002

Results

Melting point value:	350 °C
Remarks:	Decomposition is reported at 200 °C

References

IUCLID Database
reliable with restrictions

Other

Data is consistent with melting points for the class of pigments and other available measurements.

B. Boiling Point

Test Substance

Test substance:	SOLID
Remarks:	

Method

Method:	
Remarks:	

Results

Boiling point value:	
Remarks:	

References

Other

C1. Vapor Pressure

Test Substance

Test substance:	C.I. Pigment Yellow 14 (CAS NO.: 5468757) Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Estimation
Remarks:	

Results

Vapor pressure value:	2.4E-23 Pa
Temperature:	
Remarks:	

References

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

C2. Vapor Pressure

Test Substance

Test substance: Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo

Remarks:

Method

Method: Estimation Modified Grain Method

Remarks:

Results

Vapor pressure value: 2.05 E-022 mm Hg

Temperature: 25 °C

Remarks:

References MPBPWIN v. 1.41, Syracuse Research Corporation, Syracuse, New York

Other

D. Partition Coefficient

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	Octanol-water
Remarks:	

Results

Value:	8.1.mg/l
Remarks:	Calculated 2002 (EPI WIN 3.1)

References

Log Kow partition coefficient cannot be meaningfully determined for this compound and its structural surrogates, solubility in water and octanol are too low to produce a meaningful value.

Other

E. Water Solubility

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	About 5 mg of the pigment is dispersed in 30 ml of water and shaken for a period of seven hours at a controlled temperature of 80 °C, followed by a second, third and fourth period at 25 °C (16,40 and 64 hours) to approach the equilibrium between the pigment in solution and the solid. The clear solution is measured spectrophotometrically.
Remarks:	Measured Value

Results

Value:	<.02 mg/L
Temperature:	25 °C
Description:	Very Low Solubility
Remarks:	

References

Az, R., Investigations into the solubility of selected generic organic pigments in water and n-octanol, Clariant, unpublished results, July 5, 2001.

Other

The author stated that the very low solubility of pigment in water or octanol did not allow for any absorbance measurement.

Environmental Fate Endpoints

A. Photodegradation

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	

Method

Method:	Estimate
Test type:	Water\sunlight
Remarks:	

Results

Temperature:	
Degradation Rate	
: Half-life	
Ozone reaction:	3.7 ?? Hours, No ozone reaction estimation
Remarks:	

Conclusions

References

AOPWIN v. 1.91, Syracuse Research Corporation, Syracuse, New York

Other

B. Stability in Water

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	estimate
Test type:	
GLP:	
Remarks:	

Results

Half-life:	
Percent hydrolyzed in 5 days (120 hs) at 50 °C :	
Remarks:	Hydrolysis rate is extremely slow. Under the conditions of an anaerobic biodegradation test with a similar compound (biazoaryl pigment), no hydrolysis within 56 days.

Conclusions

Data Quality

Remarks:

References HYDROWIN v. 1.67, Syracuse Research Corporation, Syracuse, New York

Other

C. Biodegradation

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	OECD 301C
Test type:	Biological Oxygen Demand (BOD)
GLP:	Yes
Year:	1992
Remarks:	Degree of degradation after 28 days (Japanese standard activated sludge)

Results

Results:	C.I. Pigment Yellown13 is not readily biodegradable
Remarks:	

Conclusions

Data Quality

Remarks:

References

Madsen, T., Aerobic biodegradability of Pimatex Yellow 2GL- modified MITI test (I), VkI Water Quality Institute, 1995 (41). See also IUCLID DATASET C.I. Pigment Yellow 13.

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks: 4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-

Method

Test type: Estimation
Model used: Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
Remarks:

Results

Model data and results:

Distribution (%)	
Air	.000162
Water	.656
Soil	53.4
Sediment	45.9

Remarks:

Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

Conclusions

References

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210.

Other

The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15(9)**, 1618-1626 and 1627-1637.

IV. Ecotoxicity

A. Acute Toxicity to Fish

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was 94.5%

Method

Method:	
Test type:	OECD 203
GLP:	Flow through
Year:	yes
Species/strain:	2002
Analytical monitoring:	Bracgydanio rerio (zebrafish)
Exposure period:	Exposure solutions, temperature, pH, dissolved oxygen
Remarks:	96-Hour A group of 7 fishes were exposed to 2 nominal concentrations(0 and 100 mg/L),

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Biological observations:	
Statistical methods:	No effect, 96 hour EC-50 exceeds the maximum solubility of the test substance
Remarks:	

Conclusions Test substance is not toxic to fish

Data Quality

Reliability:	Reliable without restrictions
Remarks:	

References A. Schnurstein, Pigment Yellow 83, standard technical grade; 96 hour acute toxicity study in zebrafish (Danio rerio)/PT02-0300, Aventis Pharma Deutschland GmbH, 2002. See also IUCLID Dataset C.I. Pigment Yellow 83, p.21/54

Other

B. Acute Toxicity to Aquatic InvertebratesTest Substance

Test substance:

Remarks:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	Purity was 98.%
Test type:	
GLP:	
Year:	Directive 92/69/EC.2
Species/strain:	Static
Analytical monitoring:	Yes
Exposure period:	2002
Remarks:	Daphnia (*Daphnia magna*) Temperature, pH and dissolved oxygen 72 Hours

Results

Nominal concentration:	
Measured concentration:	
Endpoint value:	
Reproduction	100 mg/L
Biological observations:	
Statistical methods:	immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
Remarks:	

20 daphnids were exposed to2 nominal concentrations (0 and 100 mg/L)

Conclusions

Data Quality

Reliability:

Remarks:

Reliable without restrictions

References

This was a well-documented OECD guideline study conducted under GLP assurances.

Other

Migchielsen, M.H.J., Acute Toxicity Study in Daphnia Magna With C.I. Pigment Yellow 12, Project No. 341303, Notox BV, 2002

B2. Chronic Toxicity to Aquatic InvertebratesTest

Substance

Test substance:

Remarks: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo

Purity was 99.7.%

Method

Method: OECD 211
Test type: Semi -Static
GLP: Yes
Year: 1999
Species/strain: Daphnia (*Daphnia magna*)
Analytical monitoring: no
Exposure period: 21 Days
Remarks:

Results

Nominal concentration:
Measured concentration:
Endpoint value:
Reproduction
Biological observations: 0 and 1 mg/L
Statistical methods: Wilcoxon Test
Remarks: immobility 1/20 at 0 mg/L 0/20 at 100 mg/L,
No. of Living offspring 126, 115 No. of Dead offspring 32, 30

Conclusions

The test was performed at concentration far above water solubility. The particulate matter may cause physical interference with the daphnids, which may influence the results of the test. This renders the results from this test less suitable for risk assessment, but it is not expected that at maximum water solubility the substance will cause any effects.

Data Quality

Reliability: Reliable without restrictions
Remarks: This was a well-documented OECD guideline study conducted under GLP assurances.

References

Hoechst Marion Roussel, C.I. pigment Yellow 13 Daphnia Magna reproduction test, report No. 99.0405, September 1999

Other

No treatment related effects were seen.

C. Toxicity to Aquatic Plants

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity 94.5%

Method

Method:	Directive 92/69/EEC
Test type:	static
GLP:	Yes
Year:	2002
Species/strain:	Selenastrum capricornutum
Endpoint basis:	
Exposure period:	72 hours
Analytical procedures:	
Remarks:	

Results

Nominal concentration:	100 mg /L
Measured concentration:	
Endpoint value:	EC_{50} (72 hour) 190mg/L
NOEC:	equal to maximum solubility
Biological observations:	
Was control response :satisfactory	Yes
Statistical Methods:	ANOVA
Remarks:	

Conclusions No statistically significant inhibition of biomass and growth rate.

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Migchielsen, M.H.J. Fresh Water Algal Growth Inhibition Test With C.I. Pigment Yellow 83, Project No. 341292, Notox BV, 2002

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5dimethoxylphenyl)-3-oxobutyramide Purity was unknown
Remarks:	

Method

	Acute lethality; Other
Method:	LD_{50} estimate
Test type:	No (Pre-GLP)
GLP:	1972
Year:	unknown
Species/strain:	Oral gavage
Route of exposure:	5,000 & 10,000 mg/kg bw
Dose levels:	
Remarks:	

Results

	LD_{50} = >10,000 mg/kg.
Value:	
Deaths at each dose:	
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

	Reliable with restrictions
Reliability:	The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.
Remarks:	

References

Thomann P., Acute Oral Lethal Dose in Rats, Exp. No. 367/35 Ciba Geigy Ltd. 1972

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	Purity was unknown

Method

Method:	Acute lethality; OECD 401
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1984
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	5,000 mg/kg administered to animals 5 male, 5 female only 35% of the test mixture was C.I. Pigment Yellow 83

Results

Value:	
Deaths at each dose:	LD_{50} = >1,750 mg/kg.
Remarks:	

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability:	
Remarks:	Reliable with restrictions The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for these pigments and pigments of this class.

References

Rupprich, N. and Weigard, W. Colanyl-Geib HR30 Prufung der akuten oralen Toxizitat an der mannichen und weiblichen Wistar -Ratte/ 84.0243, Hoechst AG 1984

Other

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance:	Butanamide 2,2' (3,3'-dichloro 1,1'-biphenyl-4,4'diyl)bis(azo) bis N-(2-methylphenyl)-3-oxo
Remarks:	Purity was unknown

Method

Method:	Acute lethality; Other
Test type:	LD_{50} estimate
GLP:	No (Pre-GLP)
Year:	1968
Species/strain:	Rat/unknown
Route of exposure:	Oral gavage
Dose levels:	Unknown
Remarks:	

Results

Value:	LD_{50} = >5,000 mg/kg.
Deaths at each dose:	
Remarks:	

Conclusions Material would be considered as not toxic.

Data Quality

Reliability:	Reliable with restrictions
Remarks:	The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.

References Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

Repeated Dose Toxicity Test

Substance	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Test substance:	4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Remarks:	

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1979
Species/strain:	Rat RAI f SPF
Route of exposure:	Inhalation
Duration of test:	21 days + 21 day post exposure
Exposure levels:	54, 157, 410 mg/cubic meter air
Sex:	Male and female
Exposure period:	21 days
Post-exposure observation period:	21 days
Remarks:	

Results

NOAEL (NOEL): <54mg/m3
Mortality: none
Clinical signs: none observed
Slight decrease in body weight for males and females during exposure at 410 mg/m3.food consumption: no treatment related effects, ophthalmoscopic examination: no treatment related effects, Slight increase of ASAT in males at 410 mg/m3: Hematology: no treatment related effects, at 410 mg/m3 absolute and relative weight of lungs is increased for males and females on day 21 and increased relative lung weight after recovery period: some yellow discoloration of the lungs in all treated animals, Histopathology: in the lungs focal accumulation of small brown yellow infringement particles in the cytoplasm of the hystiocytic elements in the interstitium, in alveoli, bronchi and lymphohistiocytic infiltration in all animals at 410mg/m3, no regression of lung effects observed after recovery period.

Conclusions Test substance is not significantly toxic

Data Quality

Reliability: Reliable without restriction, This is a very well documented study.
Remarks:

References: Sachsse, K., 21 days aerosol inhalation toxicity study in rats, Project No. 785465, Ciba Geigy Ltd. (Switzerland), 1979. C.I. Pigment Yellow 13

Other

Repeated Dose Toxicity Test

Substance	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-
Test substance:	Commercial purity 98%
Remarks:	

Method

Method:	repeated dose
Test type:	Sub acute
GLP:	no
Year:	1984
Species/strain:	Rat
Route of exposure:	Gavage
Duration of test:	97 days
Exposure levels:	500 mg/kg bw
Sex:	Male and female
Exposure period:	
Post-exposure observation period:	
Remarks:	

Results

NOAEL (NOEL):	no treatment related changes

Conclusions Test substance is not significantly toxic

Data Quality

Reliability:	Reliable with restriction
Remarks:	

References: Colipa (1984) cited in BIBRA report 2nd Edition 1991

Other

C. **Genetic Toxicity - Mutation**

Test Substance

Test substances:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo
Remarks:	

Method

Method:	In Vitro Mutagenicity
Test type:	Ames
GLP:	No
Year:	Unknown
Species/strain:	Salmonella typhimurium
Metabolic activation:	Rat liver S9 Mix (Aroclor 1254-induced)
Concentration tested:	
Remarks:	

Results

Result:	Negative
Cytotoxic concentration:	
Precipitation concentration:	Negative
Genotoxic effects	Negative
With activation:	
Without activation:	
Statistical methods:	
Remarks:	

Conclusions Reliable with restrictions, This is a well documented study largely following OECD guideline 471

Data Quality

Reliability:	Hoechst AG, Study of the mutagenic potential of the compound T2015-26 with salmonella typhimurium (Ames Test) Report No. 575/81, 1981
Remarks:	

References

C. **Genetic Toxicity - Mutation**

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Remarks: 96.9% pure

Method

Method: OECD471

Test type: Ames

GLP: Yes

Year: 2002

Species/strain: Salmonella typhimurium TA98, TA100, TA100, TA102, TA1535 AND TA 1537

Metabolic activation: With and without

Concentration tested: 50, 60, 500, 1600, and 5000 ug/plate with and without activation

Remarks:

Results

Result: Negative in all bacterial strains with and without activation

Cytotoxic concentration:

Precipitation concentration:

Genotoxic effects

With activation: Negative Without activation: Negative Statistical methods:

Remarks:

Conclusions

Data Quality

Reliability: Reliable without restriction Remarks:

References Kauffmann, H.M. C.I. Pigment Yellow 83 Bacterial reverse mutation test (standard plate test) and prival modification (preincubation test) report No. PT02-0190, Aventis Pharma Deutschland GmbH, 2002, C.I. PIGMENT Yellow 83,

Other

D. Genetic Toxicity – Chromosomal Aberrations

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-
Remarks:	

Method

Method:	Chromosomal aberration test
Test type:	CHO cells
GLP:	no
Year:	
Species/strain:	Chinese Hamster CHL Cells
Exposure period:	
Remarks:	

Results

Result:	Negative
Genotoxic effects:	Negative
Concentration tested	Without S9 1.6, 5.0, 16, 50, and 160 ug/ml With S9 .5, 1.6,5.0,16 and 50 ug/ml
Statistical methods:	
Remarks:	

Conclusions Negative

Data Quality

Reliability:	
Remarks:	Reliable with restriction

References

Other Central Data Management NTP, NTP unpublished results, NTP/NIEHS Toxicology data on C.I. Pigment Yellow 12, , IUCLID Dataset p. 48 of 68

E. **Developmental Toxicity**

Test Substance

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-
Remarks:	4,4'diyl)bis(azo)]bis[3-oxy-N-phenyl-

Method

Method:	
GLP:	OECD 422 repeated dose developmental and reproductive
Year:	
Species/strain:	2001
Sex:	Wistar Rats
Route of exposure:	Male and Female
Exposure levels:	Gavage
Actual doses received:	0, 50, 200 and 1000 mg/kg bw
Exposure period:	
Duration of test:	Males 4 weeks, Females 6 to 7 weeks
Remarks:	

Results

Maternal toxicity

NOEL: No Mortality, body weight: no treatment related effects, food consumption: no treatment related effects, clinical signs: all females showed diarrhea including controls; feces discoloration was observed in all treated females; incidental animals of all dose groups showed lethargy, hunched posture, labored respiration, salivation, chromodacryorrhea, alopecia, scabs and piloerection, hematology RBC Hb/hematocrit increased at 50 mg/kg, clinical biochemistry: ALAT/ASAT increase at 1000 mg/kg; phosphate decreased and glucose increased at 200 mg/kg; creatinine decreased at 50 mg/kg, gross pathology incidence an severity; 1/10 greenish contents of the caecum at 1000 mg/kg , no treatment related organ weight changes no histopathologic treatment related effects, number of litters = 9 at all doses
Males, no treatment related effects body weight, food consumption and functional observations, clinical signs same as females above, hemotolgy: RBC increased at 50 mg/kg, Reproductive, successful mating ,no treatment related effects, 100% mated 9/10 pregnant per dose level, none aborting duration of gestation 21-22 days, Fetal data 9 litters at all dose levels,

Parental toxic responses:

Fetal toxic responses dose:	1000 mg/kg bw parental and reproductive
Statistical Methods:	
Remarks:	

Conclusions No treatment related reproductive effects were seen in the study. NOAEL 1000 mg/kg bw for parental and reproductive toxicity

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Combined Repeated Dose Toxiicty Study with Reproduction/ Developmental Toxicity Screening Test with C.I. Pigment Yellow 12 Administered by Oral

Other Gavage in Wistar Rats May 3, 2001, C.I. Pigment Yellow 12 p. 59 of 68

F. Toxicity to Reproduction

Test Substance See Above

Test substance:

Remarks:

Method

Method:
GLP:
Year:
Species/strain:
Sex:
Route of exposure:
Exposure levels:

Exposure period:

Duration of test:
Remarks:

Results

Maternal toxicity NOEL:
Parental toxic responses:
Fetal toxic responses dose:
Statistical Methods:
Remarks:

Conclusions

Data Quality

Reliability:
Remarks:

References

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	

Method

Method:	Irritation to the rabbit eye
Test type:	eye irritation
GLP:	yes
Year:	1996
Species/strain:	rabbit, New Zealand albino (chbb:Nzw)
Route of exposure:	
Dose levels:	
Remarks:	

Results

Value:	cornea .55, iris .33 conjunctive (redness) 2.44) (Chemosis .88)
Deaths at each dose:	
Remarks:	observation times 1,24,48,72 hours, 7 days at 24 and 72 hours and 7 days with fluorescein Reversibility within 14 days

Conclusions Slightly irritating

Data Quality

Reliability:	reliable without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Eye Irritation in the Rabbit/96.0887, Hoechst AG,1996, C.I. Pigment Yellow 83

Other

Acute toxicity

Test substance:	Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-
Remarks:	purity 79.1 %

Method

Method:	Skin irritation to the rabbit
Test type:	Skin irritation SEMIOCCLUSIVE
GLP:	yes
Year:	1996
Species/strain:	rabbit New Zealand albino
Route of exposure:	
Dose levels:	500 mg Vehicle, polyethylene glycol 400
Remarks:	

Results

Value:	slightly irritating reversibility - 7 days
Deaths at each dose:	
Remarks:	

Conclusions

Data Quality

Reliability:	Valid without restriction
Remarks:	

References Kreiling,R., Novoperm-Gelb HR04 VP2174: Test for Primary Dermal Irritation in the Rabbit / 96.0853, Hoechst AG, 1996, C.I. Pigment Yellow 83

Other

Chronic Dose Toxicity Test Substance

Test substance: Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-

Method

Method: Chronic Toxicity
Test type: Repeated oral dose
GLP: unknown
Year: 1978
Species/strain: Sprague-Dawley Rat
Route of exposure: Oral gavage
Duration of test: 104 Weeks
Exposure levels: 0, .1, .3 and .9 %
Sex: Male and Female
Exposure period:
Post-exposure observation period:
Remarks:

Results

NOAEL (NOEL): NOAEL for Rats 630 mg/kg bw, No treatment related effects, body weight, clinical signs, food consumption, necropsy and histopathology
urine analysis (no dichlorobenzidine in urine (<LOD .3 ug/ml)

No cancerous response. No toxicity or mortality as a result of exposure

Conclusions

Data Quality

Reliability: valid with restriction
Remarks:

References

Leuschner, F., Carcinogenicity Studies of Different Diarylide Yellow Pigments in Mice and Rats, Toxocol. Lett. 2, 253-260, (1978), C.I. Pigment Yellow 83.
See also, Longstaff, E., An Assessment and Categorization of the Animal Carcinogenicity Data on Selelcted Dyestuffs and an Extrapolation of Those Data to an Evaluation of the Relative Carcinogenic Risk to Man, Dyes and Pigments 4, 243-304, 1983. See also Decad, G. M. et al. Fate of Water - Insoluble and Water Soluble Dichlorobenzidine - Based Pigments in Fischer 344 Rats, Journal of Toxicology and Environmental Health, Vol. 11, pp. 455-465, 1983. (Radio labeled labeled study of C.I. Pigment Yellow 12 indicating no detectable pigment in any tissue at points up to one day.)

Other